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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,859	09/26/2003	Michael E. O'Donnell	22221/1120 (RU 339)	8720

7590 03/01/2007

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EXAMINER	
HUTSON, RICHARD G	
ART UNIT	PAPER NUMBER
1652	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/671,859	O'DONNELL ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *17-21* is/are allowed.

6)☒ Claim(s) *1,2,4-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants amendment of the specification and claims 1, cancellation of claims 3 and 6 and the addition of new claims 14-21, in the paper of 12/1/2006, is acknowledged. Claims 1, 2, 4, 5 and 7-21 are at issue and are present for examination. Applicants' arguments filed on 12/1/2006, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

It is noted to applicants that claims 4 and 5, while further limiting claim 1, from which they depend ,to those proteins comprising the amino acid sequence of SEQ ID NO: 180 and 182 (nonelected sequences), these claims continue to include the elected delta subunit and are **not** currently withdrawn as indicated by applicants status.

Claim Objections

Claims 4 and 5 are objected to because of the following informalities:

Claims 4 and 5 are objected to because they contain nonelected subject matter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The rejection of claim 7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention based upon the difference between "isolated" and

"purified" is hereby withdrawn based upon applicants arguments presented on 12/1/2006.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated n the previous office action as it applied to previous claims 1, 2 and 4-13. In response to this rejection, applicants have amended claim 1, canceled claim 3 and the added new claims 14-21 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection on the basis that the burden of establishing that an application lacks written descriptive support falls on the PTO and that this cannot be founded upon the basis of genus size alone. Applicants submit that this is the position that the PTO has taken on page 5 of the previous office action and applicants present exhibits 1-3 as evidence that the nucleic acid sequence of SEQ ID NO: 177 and the corresponding amino acid sequence of SEQ ID NO: 178 represent the claimed genus. Applicants present Genbank accessions for *Bacillus holA* nucleic acids that are homologous to the nucleotide sequence of SEQ ID NO: 177. Applicants submit that the

alignment of these sequences supports that the *holA* proteins from *Bacillus* share similar structure and therefore function.

Applicants further submit that the language recited in claim 1 is precisely the type of claim language that was acknowledged in Univ. of California v. Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) as being acceptable under written description requirement.

Applicants thus submit that based upon the above, the previous conclusion by the PTO is contrary to evidence submitted herewith by applicants and that one of ordinary skill in the art would have understood that applicants were in possession of the presently claimed invention.

Applicant's amendment and arguments are acknowledged and have been carefully considered, however have been found to be non-persuasive in overcoming the instant rejection based upon a lack of written description. While applicants argue that the presently claimed genus shares similar structure and thus function based upon this "similar structure", this conclusion remains in question. Applicant's claims are drawn to delta subunit proteins and this "function" in combination with the structural limitations of the claims is insufficient to meet the requirement for the written description of the claimed genus. It remains that applicants have not adequately described a structure-to-function relationship given that the "function" of the claimed proteins remains in question. What is the function associated with a delta subunit of a DNA polymerase III-type enzyme and how does it relate to referred to structure?

Applicants comparison to the decision in the Univ. of California v. Eli Lilly, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997) is acknowledged, however, as stated above, the recited function in the instantly claimed genus remains not as clear as that in the referred to case law, and thus any comparison to a decision based upon this is considered flawed.

Applicant is referred to the guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 1, 2 and 4-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated of delta subunit of a DNA polymerase III-type enzyme, comprising **the** amino sequence of SEQ ID NO: 178, does not reasonably provide enablement for any delta subunit of a DNA polymerase III-type enzyme from any *Bacillus* species, hybridizing to the complement of SEQ ID NO: 177 under conditions comprising 0.9M sodium citrate buffer at a temperature of 37°C. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated n the previous office action as it applied to previous claims 1, 2 and 4-13. In response to this rejection, applicants have amended claim 1, canceled claim 3 and the added new claims 14-21 and traverse the rejection as it applies to the newly amended claims.

Applicants submit that applicants provide the nucleotide sequence of *Bacillus stearothermophilus holA* (e.g., SEQ ID NO: 177) and applicant's specification describes how one of ordinary skill in the art can isolate homologs of the disclosed sequence, express the *holA* protein and test the delta subunit for the proper activity. Thus one of ordinary skill in the art would have been fully enabled to make and use the DNA molecules and their encoded protein.

Applicant's complete argument is acknowledged, however, is found non-persuasive for the reasons previously made of record and because applicants have not presented sufficient guidance as to the required function of the encoded proteins with respect to "delta subunit activity". Thus it remains that one of ordinary skill in the art would not be able to screen for such an activity, much less make and use such a majority of those encompassed proteins.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any delta subunit from any *Bacillus* species, because the specification does not establish: (A) regions of the protein structure which may be modified without effecting the desired delta subunit activity; (B) the general tolerance of a deltas subunit to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residue of a delta subunit with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful. Because of this lack of guidance, the extended experimentation that would be required to determine which substitutions

would be acceptable to retain the desired delta subunit activity and the fact that the relationship between the sequence of a peptide and its tertiary structure (i.e. its activity) are not well understood and are not predictable, it would require undue experimentation for one skilled in the art to arrive at the majority of those subunit polypeptides of the claimed having the desired biological activity.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any delta subunit from any *Bacillus* species, hybridizing to the complement of SEQ ID NO: 177 under conditions comprising 0.9M sodium citrate buffer at a temperature of 37°C. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of those proteins having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is 571-272-0930. The examiner can normally be reached on M-F, 7:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard G Hutson, Ph.D.